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**Patent Application**

of

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for

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**DIABETES MANAGEMENT SYSTEM AND METHOD FOR CONTROLLING  
BLOOD GLUCOSE**

**CONTINUATION APPLICATION INFORMATION**

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This application is a continuation in part of application  
Ser. No. 08/781,278 filed January 10, 1997, which is hereby  
incorporated by reference.

→ NOW U.S. PATENT No.  
5,956,501,

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**FIELD OF THE INVENTION**

The present invention relates generally to disease management  
systems, and in particular to a diabetes management system  
for predicting a future blood glucose value of a patient and  
for recommending a corrective action to the patient when the  
future blood glucose value lies outside of a target range.

**DESCRIPTION OF PRIOR ART**

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Insulin dependent diabetes mellitus (IDDM) is caused by the  
auto-immune destruction of the insulin producing islets of  
Langerhans in the pancreas. Insulin replacement therapy is  
the interim treatment for IDDM until such time as islet  
transplants become feasible. Insulin lowers the

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concentration of glucose in the blood, while food raises the

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concentration of glucose in the blood. The challenge of insulin therapy is to administer food and insulin in a manner which maintains blood glucose concentrations in an acceptable range, thereby avoiding hypoglycemia and hyperglycemia.

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Hyperglycemia has adverse long term consequences for the body. These consequences include kidney damage leading to kidney failure, micro-enurisms in the retina causing blindness, and the blocking of capillaries in the extremities causing an inability to heal wounds and subsequent gangrene. Hypoglycemia has an immediate adverse consequence of reduced brain function which leads to confusion and an inability to reason, remember, or react. In the extreme, hypoglycemia causes seizure, coma, and death.

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The first insulin used by diabetes patients was regular insulin taken from beef or pig pancreases. This insulin lasts for about six hours, so that patients were required to inject it three or four times per day. After World War II, longer acting insulin was developed by binding regular insulin to protamine and zinc. Regular insulin dissociates slowly from protamine and zinc, extending insulin action to twelve hours for intermediate acting insulin and twenty-four hours for ultra-lente insulin. Patients enjoyed reducing injections to one per day, but were required to modify their eating to a snack-all-day regimen to avoid hypoglycemia. The one daily insulin dose was adjusted as needed to reduce the incidence of both hypoglycemia and hyperglycemia.

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The development of portable blood glucose meters encouraged the development of more sophisticated insulin therapy regimens. One of these regimens is the split/mixed regimen which consists of two daily doses of mixed regular and intermediate acting insulins taken before breakfast and dinner. These four insulin therapy components are adjusted

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using blood glucose values measured before each meal and at  
bedtime. Patients using the split/mixed regimen are required  
to eat substantially the same meals every day so that the  
four insulin components may be adapted to the consistent meal  
5 pattern over time.

The split/mixed regimen has the advantage of allowing  
independent adjustment of insulin doses for each meal and  
requires only two injections per day. However, it has  
10 several disadvantages which are primarily due to the  
intermediate acting insulin components. The intermediate  
acting insulin taken before breakfast affects lunch time and  
pre-dinner blood glucose, requiring a patient to commit to  
the size and timing of lunch before eating breakfast. The  
15 broad action of the intermediate acting insulin may lead to  
hypoglycemia before or after lunch when the size or timing of  
the lunch is varied. Similarly, the intermediate acting  
insulin taken before dinner requires the patient to eat a  
snack at bedtime to mitigate nocturnal hypoglycemia. Even  
20 when a snack is eaten, the intermediate acting insulin may  
cause hypoglycemia around 3 AM when its action peaks.

Many of the disadvantages of the split/mixed regimen are  
overcome in a second insulin therapy regimen called the  
25 basal/bolus regimen. The basal/bolus regimen attempts to  
emulate the method by which an intact pancreas controls blood  
glucose. Normally, the intact pancreas produces a steady  
supply of basal insulin to accommodate the body's basic  
resting needs. The pancreas handles meals by releasing a  
30 sharp impulse of bolus insulin in a first phase. The sharp  
impulse of bolus insulin raises circulating insulin levels  
immediately. The first phase is followed by a sustained  
level of heightened insulin release in a second phase. The  
second phase continues until the body's blood glucose

concentration falls back to normal, at which point basal levels are obtained once again.

In the basal/bolus regimen, the basal insulin releases are emulated by two daily basal injections of intermediate acting insulin, such as Lente or Neutral Protamine Hagedorn (NPH), generally taken before breakfast and at bedtime. The bolus insulin releases are emulated by bolus injections of regular or fast acting lispro insulin taken before each meal. Fast acting lispro insulin allows the bolus injections to emulate the first phase action of the pancreas better than regular insulin by reducing the delay before the insulin injection takes effect and by shortening the overall duration of the insulin's action.

Thus, the basal/bolus regimen generally includes four insulin doses per day consisting of a pre-breakfast dose of intermediate insulin combined with regular or lispro insulin, pre-lunch and pre-dinner doses of regular or lispro insulin, and a bedtime dose of intermediate insulin. The two basal insulin doses accommodate the basic insulin needs of a patient absent any perturbations due to food. Food is handled by the bolus insulin doses, which the patient attempts to tailor to the amount of food to be eaten.

Problems arise in the basal/bolus regimen when a patient incorrectly estimates the dose of bolus insulin required for a given meal. Too little insulin causes the patient to develop hyperglycemia, while too much insulin causes the patient to develop hypoglycemia. Hypoglycemia or hyperglycemia may also result when the size of the meal is varied without adequate adjustment of the bolus insulin dose. Patients using the basal/bolus regimen are typically required to eat substantially the same meals every day so that the

bolus insulin doses may be adapted to the consistent meal pattern over time.

Several electronic diabetes management systems have been developed to assist patients in the implementation of the split/mixed or basal/bolus regimens. One such system is disclosed in U.S. Patent 5,019,974 issued to Beckers on May 28, 1991. Beckers describes a master computer for developing a therapy program for a patient and for downloading the therapy program to a patient-operated recorder. The recorder reminds the patient of any therapy due and records that the therapy has been performed by the patient. Data from the recorder is subsequently fed back to the master computer to improve or alter the therapy program.

In using Beckers' system, a patient must strictly adhere to the predetermined therapy guidelines in order for the therapy program to be effective. To make any therapy adjustments, the patient must upload data to the master computer, wait for the therapy adjustments, and strictly follow the adjusted guidelines. Thus, Beckers' system restricts the patient to a consistent meal plan, with no flexibility for adjusting the therapy program to meals of varying size or timing.

Following a consistent meal plan is extremely difficult, whether for diabetes treatment or weight loss. Rarely can a patient stick to a predetermined meal plan every day of his or her life. Consequently, Beckers' system is ineffective for assisting the patient in controlling blood glucose and avoiding hypoglycemia or hyperglycemia when the patient deviates from the plan during his or her normal course of behavior.

Moreover, Beckers' system lacks any mechanism for predicting the patient's future blood glucose concentration and is thus

unable to alert the patient to future hypoglycemia or hyperglycemia resulting from an unusual meal or an incorrectly estimated insulin dose taken for the meal. Further, Beckers does not teach or describe any mechanism for recommending to the patient a corrective action, such as a supplemental insulin dose or carbohydrate supplement, when the patient has a potential for future hypoglycemia or hyperglycemia.

Another diabetes management system is disclosed in U.S. Patent 4,731,726 issued to Allen on March 15, 1988. Allen describes a system which includes a physician computer for downloading therapy guidelines to a patient-operated apparatus. The apparatus includes a blood glucose meter for recording a patient's blood glucose values and keys for entering patient data relating to diet, insulin, exercise, stress, and symptoms of illness. The apparatus is programmed to recommend insulin doses to the patient based upon the data supplied.

Unfortunately, Allen's system recommends insulin doses to the patient based upon pre-meal blood glucose values only, as stated in column 16, lines 42 - 44. This forces the patient to wait until the next meal before he or she may take action to correct hypoglycemia or hyperglycemia developed since the previous meal. Further, Allen's system has no mechanism for predicting the patient's future blood glucose concentration based upon the patient's post-meal blood glucose value and the insulin action remaining from insulin doses injected before the meal. As a result, Allen's system is unable to alert the patient to future hypoglycemia or hyperglycemia resulting from the patient eating an unusual meal or taking an incorrect insulin dose for the meal.

## OBJECTS AND ADVANTAGES OF THE INVENTION

In view of the above, it is an object of the present invention to provide a diabetes management system for  
5 predicting a future blood glucose concentration of a patient based upon the patient's current blood glucose concentration and the insulin action remaining from previous insulin doses, thereby enabling the patient to take timely corrective action to prevent hypoglycemia or hyperglycemia. It is another  
10 object of the invention to provide a diabetes management system for recommending the corrective action to the patient when the predicted blood glucose value lies outside of a target range.

15 These and other objects and advantages will become more apparent after consideration of the ensuing description and the accompanying drawings.

## SUMMARY

20 The invention presents a system and method for assisting a patient having diabetes mellitus in controlling blood glucose. The system includes a patient-operated apparatus having a blood glucose meter for measuring a blood sample of  
25 the patient and for producing from a measurement of the blood sample a blood glucose value  $G(t_d)$  representative of a blood glucose concentration of the patient at time  $t_d$ . The apparatus also includes a user interface for entering in the apparatus an insulin dose value  $I_k$  representative of an  
30 insulin dose administered to the patient prior to time  $t_d$ .

The apparatus further includes a memory for storing maximum and minimum values defining a target blood glucose range of the patient. The memory also stores a target blood glucose  
35 value of the patient within the range, an insulin sensitivity

value representative of an insulin sensitivity of the patient, and information for determining an insulin action value  $F_k(t_d)$  representative of a fraction of insulin action remaining at time  $t_d$  from the insulin dose.

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A processor is connected to the glucose meter, user interface, and memory. The processor is programmed to determine the insulin action value  $F_k(t_d)$  and to determine a future blood glucose value  $G(t_j)$  representative of an

10 expected blood glucose concentration of the patient at time  $t_j$ . The processor determines the future blood glucose value  $G(t_j)$  in dependence upon the blood glucose value  $G(t_d)$ , the insulin dose value  $I_k$ , the insulin sensitivity value, and the insulin action value  $F_k(t_d)$ . The processor is also programmed  
15 to determine a corrective action for the patient when the future blood glucose value  $G(t_j)$  lies outside of the target range.

20 The corrective action is preferably an administration of a supplemental insulin dose when the future blood glucose value  $G(t_j)$  lies above the target range or a consumption of a number of grams of carbohydrates when the future blood glucose value  $G(t_j)$  lies below the target range. The processor is programmed to determine the supplemental insulin  
25 dose in dependence upon the insulin sensitivity value and a difference between the future blood glucose value  $G(t_j)$  and the target blood glucose value. The processor is further programmed to determine the number of grams of carbohydrates to be consumed in dependence upon the difference between the  
30 future blood glucose value  $G(t_j)$  and the target blood glucose value. A display is connected to the processor for displaying the future blood glucose value  $G(t_j)$  and for recommending the corrective action to the patient.



The system also includes a healthcare provider computer in communication with the apparatus for receiving from the apparatus blood glucose values and insulin dose values and for calculating from the values an adjusted insulin sensitivity value for the patient. The apparatus includes a communication device, such as a modem and input/output port, connected to the processor for establishing a communication link between the apparatus and the healthcare provider computer, for transmitting the blood glucose values and insulin dose values through the communication link, and for receiving through the communication link the adjusted insulin sensitivity value.

#### BRIEF DESCRIPTION OF THE DRAWINGS

- FIG. 1 is a top plan view of a patient-operated apparatus according to the invention.
- FIG. 2 is a schematic block diagram of the apparatus of FIG. 1 connected to a healthcare provider computer through a communication network.
- FIG. 3 is a schematic diagram of the apparatus of FIG. 1 connected to the healthcare provider computer of FIG. 2 through a connection cord.
- FIG. 4 is a sample parameter value entry window as it appears on a display of the apparatus of FIG. 1.
- FIG. 5 is a graph illustrating the percent of insulin action remaining from regular and fast acting insulins as a function of time after injection.
- FIG. 6A is a sample table showing fractions of insulin action remaining from a dose of regular insulin at corresponding time points after injection.
- FIG. 6B is a continuation of the table of FIG. 6A.
- FIG. 7 is a sample table showing fractions of insulin action remaining from a dose of fast acting insulin at corresponding time points after injection.

FIG. 8A is a flow chart illustrating steps included in a computer program executed by the apparatus of FIG. 1.

FIG. 8B is a continuation of the flow chart of FIG. 8A.

5 FIG. 9A is a flow chart illustrating steps included in a prediction program module of the computer program of FIGS. 8A and 8B.

FIG. 9B is a continuation of the flow chart of FIG. 9A.

10 FIG. 10 is a flow chart illustrating steps included in a graph program module of the computer program of FIGS. 8A and 8B.

#### DETAILED DESCRIPTION

15 The present invention is a diabetes management system and method for predicting a future blood glucose value of a patient and for recommending to the patient a corrective action when the future blood glucose value lies outside of a target blood glucose range. In the following description,  
20 numerous specific details are set forth in order to provide a thorough understanding of the present invention. However, it will be apparent to one of ordinary skill in the art that these specific details need not be used to practice the invention. In other instances, well known structures,  
25 interfaces, and processes are not shown in detail to avoid unnecessarily obscuring the present invention.

FIGS. 1 - 7 illustrate a diabetes management system according to a preferred embodiment of the invention. Referring to  
30 FIG. 1, the diabetes management system includes a patient-operated apparatus 10 having a housing 12 for holding the components of apparatus 10. Housing 12 is preferably sufficiently compact to enable apparatus 10 to be hand-held and carried by a patient. A strip guide 18 for receiving a  
35 blood glucose test strip 20 is located on a surface of

housing **12**. Test strip **20** is for receiving a blood sample from the patient.

Apparatus **10** includes a display **14** for displaying predicted  
5 future blood glucose values and for recommending to the  
patient corrective actions when the future blood glucose  
values lie outside of a target blood glucose range. Display  
**14** is preferably a liquid crystal display (LCD). Display **14**  
is also designed to display prompts and a menu **46** to the  
10 patient during the operation of apparatus **10**.

Menu **46** preferably includes a number of menu options as  
follows. The "DOSE" option starts a procedure for entering  
in apparatus **10** insulin dose values representative of insulin  
15 doses administered to the patient. Each insulin dose is  
typically self-injected by the patient. After injecting a  
dose, the patient selects the "DOSE" option to record in  
apparatus **10** the dose value and the type of insulin injected.  
The "TEST BG" option starts a procedure for measuring a  
20 current blood glucose value of the patient. The "PREDICT"  
option starts a procedure for predicting a future blood  
glucose value of the patient.

The "VALUES" option starts a procedure for entering in  
25 apparatus **10** various parameter values used to predict the  
future blood glucose values and to recommend appropriate  
corrective actions to the patient. The "SEND" option starts  
a procedure for transmitting the blood glucose values and  
insulin dose values stored in apparatus **10** to a healthcare  
30 provider computer. The "RECEIVE" option starts a procedure  
for receiving data from the healthcare provider computer.

Display **14** is also designed to display the predicted future  
blood glucose values in graphical form. Display **14**  
35 preferably displays a graph **48** which includes a blood glucose

value curve **50** generated from the predicted blood glucose values. Graph **48** also includes a hypoglycemic line **52** indicating a hypoglycemic threshold of the patient and a hyperglycemic line **53** indicating a hyperglycemic threshold of the patient. Apparatus **10** also includes an audio transducer, such as a speaker **54**, for audibly alerting the patient when a predicted future blood glucose value lies below the hypoglycemic threshold.

Apparatus **10** further includes a keypad **16** having a number of keys as follows. The ON/OFF key is pressed to turn apparatus **10** on and off. Number keys 0, 1, 2, 3, etc. are used for entering information on display **14**, such as insulin dose values, insulin types, and dates and times of injections. The ENTER key is used after operation of the number keys to enter the information in apparatus **10**. The ENTER key is also used to select menu options. The CLEAR key is used to clear numbers which have been entered incorrectly. The YES and NO keys are pressed in response to prompts on display **14** which require a yes or no answer.

The MENU key is pressed to display menu **46** on display **14**. The ARROW keys are for scrolling through the menu options. Specific techniques for manufacturing and using an electronic apparatus having these keys are well known in the art. Further, those skilled in the art will recognize that the keys may be replaced by other user controls, such as switches, buttons, or graphic controls implemented on a touch sensitive screen.

FIG. 2 is a schematic block diagram illustrating apparatus **10** in greater detail. Apparatus **10** includes a microprocessor **22** and a memory **24** connected to microprocessor **22**. Microprocessor **22** is designed to execute a computer program stored in memory **24** to perform the various calculations and

control functions which are described in the operation section below.

Keypad **16** is connected to microprocessor **22** through a standard keypad decoder **26**. Display **14** is connected to microprocessor **22** through a display driver **30**. Microprocessor **22** communicates with display driver **30** via an interface, and display driver **30** updates and refreshes display **14** under the control of microprocessor **22**. Speaker **54** and a clock **56** are also connected to microprocessor **22**. Speaker **54** operates under the control of microprocessor **22** to emit audible tones alerting the patient to possible future hypoglycemia. Clock **56** supplies the current date and time to microprocessor **22**.

Memory **24** also stores blood glucose values of the patient, the insulin dose values, the insulin types, and the parameter values used by microprocessor **22** to calculate future blood glucose values, supplemental insulin doses, and carbohydrate supplements. Each blood glucose value and insulin dose value is stored in memory **24** with a corresponding date and time. Memory **24** is preferably a non-volatile memory, such as an electrically erasable read only memory (EEPROM).

Apparatus **10** also includes a blood glucose meter **28** connected to microprocessor **22**. Glucose meter **28** is designed to measure blood samples received on blood glucose test strips and to produce blood glucose values from measurements of the blood samples. Such glucose meters are well known in the art. Glucose meter **28** is preferably of the type which produces digital values which are output directly to microprocessor **22**. Alternatively, blood glucose meter **28** may be of the type which produces analog values. In this alternative embodiment, blood glucose meter **28** is connected

to microprocessor **22** through an analog to digital converter (not shown).

Apparatus **10** further includes an input/output port **34**,  
5 preferably a serial port, which is connected to  
microprocessor **22**. Port **34** is connected to a modem **32** by an  
interface, preferably a standard RS232 interface. Modem **32**  
is for establishing a communication link between apparatus **10**  
10 and a healthcare provider computer **38** through a communication  
network **36**. Modem **32** is capable of transmitting data to and  
receiving data from provider computer **38** through  
communication network **36**. In the preferred embodiment,  
communication network **36** is a telephone network and modem **32**  
15 establishes the communication link to computer **38** through  
telephone lines.

Referring to FIG. 3, the input/output port may also be used  
to establish an alternative communication link between  
apparatus **10** and computer **38** through a data connection cord  
20 **40**. Connection cord **40** is connectable to the input/output  
port of apparatus **10** and to a corresponding input/output port  
of healthcare provider computer **38**. Specific techniques for  
connecting electronic devices through connection cords are  
well known in the art.

25 Healthcare provider computer **38** is preferably a personal  
computer located at a healthcare provider site, such as the  
office of the patient's physician. Healthcare provider  
computer **38** is designed to receive the patient's blood  
30 glucose values and insulin dose values from apparatus **10** and  
calculate from the values an adjusted insulin sensitivity  
value for the patient, as will be explained in the operation  
section below.

The computer program executed by microprocessor 22 includes equations for calculating future blood glucose values, supplemental insulin doses, and carbohydrate supplements. The variables used in the computer program are defined as follows:

$t_1, t_2, \dots, t_d, \dots, t_j, \dots, t_M$  = time points.

$G(t_d)$  = blood glucose value representative of a blood glucose concentration of the patient at time  $t_d$ .

$G(t_j)$  = future blood glucose value representative of an expected blood glucose concentration of the patient at time  $t_j$ .

$I_k$  = insulin dose value representative of an insulin dose  $k$  administered to the patient prior to time  $t_d$ , where  $k = 1$  to  $N$  and  $N$  = the total number of bolus and supplemental insulin doses administered to the patient. Insulin dose value  $I_k$  is preferably expressed in units of insulin.

$P_k$  = insulin type of insulin dose  $k$ , e.g. regular insulin or fast acting lispro insulin.

$F_k(t_d)$  = insulin action value representative of the fraction of insulin action remaining at time  $t_d$  from insulin dose  $k$ . For the purposes of this specification and the appended claims, insulin action is defined as the action of insulin to lower a patient's blood glucose concentration.

$F_k(t_j)$  = insulin action value representative of a fraction of insulin action remaining at time  $t_j$  from insulin dose  $k$ .





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$$G(t_j) = G(t_d) - S \left[ \sum_{k=1}^N I_k (F_k(t_d) - F_k(t_j)) \right] \quad (1)$$

Microprocessor 22 calculates future blood glucose value  $G(t_j)$  from blood glucose value  $G(t_d)$ , insulin sensitivity value  $S$ , insulin dose value  $I_k$ , and insulin action values  $F_k(t_d)$  and  $F_k(t_j)$ . If the patient has injected multiple insulin doses, their remaining action is summed as shown. Blood glucose value  $G(t_d)$  is preferably measured a sufficient time after the patient's last meal to ensure that most or all of the meal has already been absorbed. A sufficient time is usually two hours after a typical meal, or one hour after a snack or smaller meal.

FIG. 4 shows a sample parameter value entry window 58 as it appears on display 14. Window 58 is preferably a pop-up window displayed when the patient selects the "VALUES" option from the menu. Window 58 includes data entry fields 60 for entering in apparatus 10 insulin sensitivity value  $S$ , carbohydrate value  $C$ , hypoglycemic value  $H$ , maximum value  $R_{max}$ , minimum value  $R_{min}$ , and target value  $T$ . The patient navigates between entry fields 60 using the arrow keys on the keypad.

Apparatus 10 uses information derived from insulin time activity profiles to determine the insulin action values. The time activity profiles of insulin are described in several sources, such as Eli Lilly and Company's website [http://www.lilly.com/diabetes/ref\\_manual/insulin\\_bck.html](http://www.lilly.com/diabetes/ref_manual/insulin_bck.html). The time activity profiles of insulin are also described in Howey et al. "A Rapidly Absorbed Analogue of Human Insulin", *Diabetes*, Vol. 43, pp. 396-402, 1994, which is hereby incorporated by reference.

FIG. 5 is a graph illustrating the percent of insulin action remaining from doses of regular and lispro insulins as a function of time after injection. The graph includes two insulin action curves derived from data in Howey et al. A first insulin action curve **42** shows the percent of insulin action remaining from a dose of regular insulin as a function of time after injection. A second insulin action curve **44** shows the percent of insulin action remaining from a dose of lispro insulin as a function of time after injection.

An insulin action value is determined from curves **42** or **44** by determining the time after injection, locating the corresponding percentage of insulin action remaining on the appropriate curve, and dividing the percentage by 100 to yield the insulin action value. For example, if the patient injected a dose of lispro and the time after injection equals 150 minutes, then the insulin action value is determined to be 0.40 from curve **44**. This indicates that at 150 minutes after injection, the insulin dose has 40% of its full insulin action remaining to lower the patient's blood glucose concentration.

The insulin action curves shown in FIG. 5 are derived from standard patient data. An insulin action curve customized to an individual patient may be generated experimentally by establishing basal homeostasis in the patient and then measuring the effect of a supplemental insulin dose on the patient's blood glucose concentration. After injecting the supplemental insulin dose, the patient's blood glucose is measured frequently over the period of time required for the insulin to be fully absorbed.

The measured blood glucose values are used to generate a curve of the patient's blood glucose concentration as a function of time after injection. The total blood glucose

drop resulting from the supplemental insulin dose is determined by subtracting the last blood glucose value from the first blood glucose value. The curve is normalized by subtracting the final blood glucose value from each point on the curve and dividing the result by the total blood glucose drop. Normalizing the curve in this manner yields an insulin action curve individualized to the patient. This experiment is repeated, preferably at varying times of day, to generate a continuous insulin action curve for the patient.

In the preferred embodiment, information for determining insulin action values  $F_k(t_d)$  and  $F_k(t_j)$  is stored in memory **24** in tabular form. The information may be derived from standard insulin action curves or derived from an insulin action curve individualized to the patient. FIGS. 6A and 6B show a first insulin action Table 1 which is derived from curve **42**, the insulin action curve for regular insulin.

FIG. 7 shows a second insulin action Table 2 which is derived from curve **44**, the insulin action curve for lispro insulin. Each insulin action table includes a first column containing time points after injection and a second column containing corresponding insulin action values. Microprocessor **22** preferably uses linear interpolation to determine insulin action values  $F_k(t_d)$  and  $F_k(t_j)$  from the insulin action tables, as will be described in the operation section below.

The operation of the preferred embodiment is illustrated in FIGS. 1 - 10. Referring to FIG. 2, a preferred method of using the diabetes management system to assist a patient having diabetes mellitus in controlling blood glucose includes the step of storing in memory **24** insulin sensitivity value **S**, carbohydrate value **C**, hypoglycemic value **H**, maximum value **R<sub>max</sub>**, minimum value **R<sub>min</sub>**, target blood glucose value **T**, and the table values for determining remaining insulin action

at corresponding times after injection. The values may be entered in apparatus **10** through input/output port **34** or keypad **16**. The values stored in memory **24** are preferably selected under the supervision of a healthcare provider, such as the patient's physician.

Insulin sensitivity value **S** is preferably customized to the patient based upon the patient's measured blood glucose values and insulin dose values, as will be explained in detail below. However, when the patient is first provided with apparatus **10**, historical blood glucose values and insulin dose values may not be available. In this case, insulin sensitivity value **S** is preferably estimated by dividing 1,500 mg/dl by the patient's total daily insulin need. For example, if the patient's total daily insulin need is 30 units, the initial insulin sensitivity value is calculated as 50 mg/dl per unit of insulin.

Specific techniques for establishing carbohydrate value **C**, hypoglycemic value **H**, maximum value **R<sub>max</sub>**, minimum value **R<sub>min</sub>**, and target blood glucose value **T** are well known in the art. For example, many physicians prefer a target blood glucose range of 100 - 150 mg/dl with a target blood glucose value of 120 mg/dl and a hypoglycemic value of 70 mg/dl. Carbohydrate value **C** is preferably selected in dependence upon the patient's weight. For example, one gram of carbohydrates typically raises blood glucose concentrations by 3 mg/dl, 4 mg/dl, and 5 mg/dl for people who weigh 90 kg, 70 kg, and 45 kg, respectively.

Apparatus **10** is used by the patient to predict a future blood glucose value and to generate a corrective action when the predicted value lies outside of the patient's target blood glucose range. FIG. 8A is a flow chart illustrating steps included in the computer program executed by microprocessor

22 to perform these functions. FIG. 8B is a continuation of the flow chart of FIG. 8A.

In step 102, microprocessor 22 determines if the patient has selected the "DOSE" option from menu 46. If the patient has not selected the "DOSE" option, microprocessor 22 proceeds to step 106. If the patient has selected the "DOSE" option, microprocessor 22 proceeds to step 104, entering and storing dose value  $I_k$  and insulin type  $P_k$ .

To enter and store dose value  $I_k$  and insulin type  $P_k$ , microprocessor 22 displays the prompt "ENTER DOSE IN UNITS OF INSULIN" on display 14. The patient then enters dose value  $I_k$  into microprocessor 22 through keypad 16. The patient is then prompted with "ENTER INSULIN TYPE: PRESS 1 FOR REGULAR OR 2 FOR LISPRO". The patient enters insulin type  $P_k$  into microprocessor 22 by pressing the key corresponding to the insulin type injected.

Microprocessor 22 then prompts the patient with "ENTER DATE/TIME OF INJECTION OR PRESS 1 FOR CURRENT DATE/TIME". The patient enters the date and time of injection or selects the current date and time if the dose entry is made immediately after the injection. Microprocessor 22 stores dose value  $I_k$  and insulin type  $P_k$  in memory 24 with the selected date and time. Following step 104, microprocessor 22 proceeds to step 106.

In step 106, microprocessor 22 determines if the patient has selected the "TEST BG" option from menu 46. If the patient has not selected the "TEST BG" option, microprocessor 22 proceeds to step 118. If the patient has selected the "TEST BG" option, microprocessor 22 prompts the patient to place a blood sample on a blood glucose test strip and to insert the test strip in strip guide 18, step 108.

Glucose meter **28** measures the blood sample and produces blood glucose value  $G(t_d)$  from the measurement of the blood sample.

In step **110**, blood glucose value  $G(t_d)$  is entered in

5 microprocessor **22** by glucose meter **28**, coded and labeled with the date and time of the measurement, and stored in memory **24**. Blood glucose value  $G(t_d)$  is also displayed to the patient on display **14** in step **112**.

10 In step **114**, microprocessor **22** determines if the patient has selected the "PREDICTION" option from menu **46**. If the patient has not selected the "PREDICTION" option, microprocessor **22** proceeds to step **118**. If the patient has selected the "PREDICTION" option, microprocessor **22** executes  
15 a future blood glucose value program module in step **116**. The steps included in the future blood glucose value program module are illustrated in the flow chart of FIGS. 9A and 9B and will be described in detail below. After executing the program module of step **116**, microprocessor **22** proceeds to  
20 step **118**.

In step **118**, microprocessor **22** determines if the patient has selected the "VALUES" option from menu **46**. If the patient has not selected the "VALUES" option, microprocessor **22**  
25 proceeds to step **124**. If the patient has selected the "VALUES" option, microprocessor **22** displays on display **14** the parameter value entry window **58**, step **120**. In step **122**, the parameter values are entered in microprocessor **22** through keypad **16** and stored in memory **24**. Following step **122**,  
30 microprocessor **22** proceeds to step **124**.

In step **124**, microprocessor **22** determines if the patient has selected the "SEND" option from menu **46**. If the patient has not selected the "SEND" option, microprocessor **22** proceeds to  
35 step **128**. If the patient has selected the "SEND" option,

microprocessor 22 prompts the patient to connect modem 32 to a telephone line. Microprocessor 22 then transmits the blood glucose values and insulin dose values stored in memory 24 to healthcare provider computer 38 through network 36, step  
5 126. Microprocessor 22 then proceeds to step 128.

In step 128, microprocessor 22 determines if the patient has selected the "RECEIVE" option from menu 46. If the patient has not selected the "RECEIVE" option, microprocessor 22  
10 returns to step 102 and repeats the program steps until apparatus 10 is turned off by the patient. If the patient has selected the "RECEIVE" option, microprocessor 22 prompts the patient to connect modem 32 to a telephone line. In step  
15 130, microprocessor 22 receives data from healthcare provider computer 38 through network 36.

The data preferably includes an adjusted insulin sensitivity value and may optionally include new maximum and minimum values defining the patient's target blood glucose range, a  
20 new target blood glucose value, and new insulin action table values for determining remaining insulin action. In step 132, microprocessor 22 stores the received data in memory 24 for use in subsequent calculations. Following step 132, microprocessor 22 returns to step 102 and repeats the program  
25 steps until apparatus 10 is turned off by the patient.

FIGS. 9A and 9B illustrate the steps included in the future blood glucose value program module of step 116. In step  
30 202, microprocessor 22 determines if the patient wishes to see future blood glucose value  $G(t_j)$  predicted for a default ultimate time point by displaying the prompt "USE ULTIMATE TIME IN PREDICTION? YES/NO?". In the preferred embodiment, the ultimate time point is the time point at which the last insulin dose  $k$  injected by the patient will be fully absorbed  
35 and have no insulin action remaining. In response to a NO

input from the patient, microprocessor **22** proceeds to step **208**. In response to a YES input from the patient, microprocessor **22** sets time  $t_j$  equal to the ultimate time point, step **204**.

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To set time  $t_j$  equal to the ultimate time point, microprocessor **22** retrieves from memory **24** the last insulin dose value  $I_k$  and corresponding insulin type  $P_k$  entered by the patient. If the insulin type  $P_k$  is regular insulin,

10 microprocessor **22** retrieves from Table 1 the time after injection value corresponding to 0.00 insulin action remaining, i.e. 720 minutes. If the insulin type  $P_k$  is lispro insulin, microprocessor **22** retrieves from Table 2 the time after injection value corresponding to 0.00 insulin  
15 action remaining, i.e. 390 minutes.

Microprocessor **22** adds the retrieved time after injection value to the time of injection stored with the last dose value  $I_k$  and sets time  $t_j$  equal to the sum. When time  $t_j$  is  
20 selected to be the ultimate time point, each insulin dose  $k$  injected by the patient will have no remaining insulin action at time  $t_j$ . Accordingly, microprocessor **22** sets insulin action value  $F_k(t_j)$  equal to 0 for each dose value  $I_k$  stored in memory **24**, step **206**. Following step **206**, microprocessor  
25 **22** proceeds to step **212**.

If the patient has not selected the ultimate time point for time  $t_j$ , microprocessor **22** prompts the patient to specify time  $t_j$  by displaying "ENTER TIME FOR PREDICTION". The  
30 patient then enters time  $t_j$  in microprocessor **22** in step **208**. In step **210**, microprocessor **22** determines insulin action values  $F_k(t_j)$  for each dose value  $I_k$  stored in memory **24**. Microprocessor **22** preferably determines insulin action values  $F_k(t_j)$  using linear interpolation.

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The insulin action value  $F_k(t_j)$  for each dose value  $I_k$  is also determined in dependence upon its corresponding insulin type  $P_k$ . If the insulin type is regular insulin, microprocessor 22 determines the insulin action value  $F_k(t_j)$  by interpolating between the values listed in Table 1. If the insulin type is lispro insulin, microprocessor 22 determines the insulin action value  $F_k(t_j)$  by interpolating between the values listed in Table 2.

The interpolation is preferably performed as follows. For each dose value  $I_k$ , microprocessor 22 calculates a time after injection value  $X_k$  indicating the time differential between time  $t_j$  and the time of injection of dose  $k$ . Microprocessor 22 then retrieves four values from the appropriate insulin action table. The four values retrieved are a first time after injection value  $X_0$  and its corresponding insulin action value  $Y_0$ , and a second time after injection value  $X_1$  and its corresponding insulin action value  $Y_1$ .

Value  $X_0$  is selected from the appropriate table as the time after injection value which is closest to value  $X_k$  without exceeding value  $X_k$ . Value  $X_1$  is selected as the time after injection value in the next row of the table. Microprocessor 22 preferably calculates the insulin action value  $F_k(t_j)$  for each dose value according to equation (2A):

$$F_k(t_j) = Y_0 + \frac{(X_k - X_0)(Y_1 - Y_0)}{(X_1 - X_0)} \quad (2A).$$

For example, if the patient enters a dose value indicating a dose of regular insulin was injected at 12:00 PM and specifies a time  $t_j$  of 2:20 PM, microprocessor 22 first calculates time after injection value  $X_k$  to be 140 minutes. Microprocessor 22 then retrieves from Table 1 the values  $X_0 = 135$  minutes,  $Y_0 = 0.70$ ,  $X_1 = 150$  minutes, and  $Y_1 = 0.64$ .

Microprocessor 22 calculates insulin action value  $F_k(t_j)$  for the dose from equation (2A) as:

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$$F_k(t_j) = 0.70 + \frac{(140 - 135)(0.64 - 0.70)}{(150 - 135)} = 0.68$$

Microprocessor 22 thus determines that the regular insulin dose injected at 12:00 PM will have 68% of its insulin action remaining at 2:20 PM. Specific techniques for performing linear interpolations in this manner are well known in the art. Further, those skilled in the art will recognize that the insulin action tables could be provided with shorter time intervals between the time points to provide as much precision and accuracy as desired in the interpolation.

15 In step 212, microprocessor 22 performs a similar linear interpolation to determine the insulin action values  $F_k(t_d)$  for each dose value  $I_k$  stored in memory 24. The insulin action value  $F_k(t_d)$  for each dose value  $I_k$  is also determined in dependence upon its corresponding insulin type  $P_k$ . If the insulin type is regular insulin, microprocessor 22 determines the value  $F_k(t_d)$  by interpolating between the values listed in Table 1. If the insulin type is lispro insulin, microprocessor 22 determines the value  $F_k(t_d)$  by interpolating between the values listed in Table 2.

25 For each dose value  $I_k$ , microprocessor 22 calculates a time after injection value  $Z_k$  indicating the time differential between time  $t_d$  and the time of injection of dose  $k$ .

30 Microprocessor 22 then retrieves from the appropriate insulin action table the first time after injection value  $X_0$ , the corresponding insulin action value  $Y_0$ , the second time after injection value  $X_1$ , and the corresponding insulin action value  $Y_1$ . Value  $X_0$  is selected from the appropriate table as the time after injection value which is closest to value  $Z_k$

without exceeding value  $Z_k$ . Value  $X_1$  is selected as the time after injection value in the next row of the table.

Microprocessor 22 calculates each insulin action value  $F_k(t_d)$  according to equation (2B):

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$$F_k(t_d) = Y_0 + \frac{(Z_k - X_0)(Y_1 - Y_0)}{(X_1 - X_0)} \quad (2B).$$

For example, if the patient enters a dose value indicating a dose of lispro insulin was injected at 8:30 PM and time  $t_d$  is

10 11:00 PM, microprocessor 22 first calculates time after injection value  $Z_k$  to be 150 minutes. Microprocessor 22 then retrieves from Table 2 the values  $X_0 = 150$  minutes,  $Y_0 = 0.40$ ,  $X_1 = 165$  minutes, and  $Y_1 = 0.32$ . Microprocessor 22 calculates insulin action value  $F_k(t_d)$  for the dose from  
15 equation (2B) as:

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$$F_k(t_d) = 0.40 + \frac{(150 - 150)(0.32 - 0.40)}{(165 - 150)} = 0.40$$

Microprocessor 22 thus determines that the lispro insulin  
20 dose injected at 8:30 PM has 40% of its insulin action remaining at 11:00 PM. In step 214, microprocessor 22 calculates predicted future blood glucose value  $G(t_j)$  according to equation (1):

7/0280

$$G(t_j) = G(t_d) - S \left[ \sum_{k=1}^N I_k(F_k(t_d) - F_k(t_j)) \right] \quad (1)$$

Future blood glucose value  $G(t_j)$  is then displayed to the patient on display 14, step 216. In step 218, microprocessor 22 determines if the patient wishes to see  
30 graph 48 by displaying the prompt "DISPLAY GRAPH? YES/NO?". In response to a NO input from the patient, microprocessor 22

proceeds to step 222. In response to a YES input from the patient, microprocessor 22 executes a graph program module in step 220. The steps included in the graph program module are illustrated in the flow chart of FIG. 10 and will be described in detail below. After executing the program module of step 220, microprocessor 22 proceeds to step 222.

In step 222, microprocessor 22 compares future blood glucose value  $G(t_j)$  to maximum value  $R_{max}$  and minimum value  $R_{min}$  to determine if future blood glucose value  $G(t_j)$  lies outside of the patient's target blood glucose range. If glucose value  $G(t_j)$  does not lie outside of the target range, "NO CORRECTIVE ACTION REQUIRED" is displayed to the patient in step 224. Following step 224, the future blood glucose value program module ends.

If glucose value  $G(t_j)$  lies outside of the target range, microprocessor 22 determines a corrective action for the patient and recommends the corrective action to the patient on display 14. In step 226, microprocessor 22 determines if glucose value  $G(t_j)$  is greater than maximum value  $R_{max}$ . If glucose value  $G(t_j)$  is not greater than maximum value  $R_{max}$ , microprocessor 22 proceeds to step 234.

If glucose value  $G(t_j)$  is greater than maximum value  $R_{max}$ , microprocessor 22 calculates a supplemental insulin dose  $D$  for the patient and displays insulin dose  $D$  on display 14, step 228. Microprocessor 22 preferably calculates supplemental insulin dose  $D$  in dependence upon insulin sensitivity value  $S$  and a difference between future blood glucose value  $G(t_j)$  and target blood glucose value  $T$  according to equation (3):

$$D = (G(t_j) - T) / S \quad (3).$$

After displaying supplemental insulin dose **D**, microprocessor **22** determines if the patient wishes to enter a dose value for the supplemental insulin dose by displaying the prompt

"SUPPLEMENTAL INSULIN TAKEN? YES/NO?", step **230**. In response

to a NO input from the patient, the program module ends. In response to a YES input, microprocessor **22** proceeds to step **232**, entering and storing the dose value and insulin type of supplemental insulin dose **D**. Step **232** is analogous to step **104** previously described with reference to FIG. 7A.

Following step **232**, the program module ends.

In step **234**, microprocessor **22** determines if glucose value  $G(t_j)$  is less than hypoglycemic value **H**. If future blood glucose value  $G(t_j)$  is not less than hypoglycemic value **H**, microprocessor **22** proceeds to step **240**. If glucose value  $G(t_j)$  lies below hypoglycemic value **H**, microprocessor **22** audibly alerts the patient by causing speaker **54** to emit audible tones, step **236**. This alerts the patient that he or she is likely to develop hypoglycemia unless a carbohydrate supplement is taken.

In step **238**, microprocessor **22** calculates a number **B** of grams of carbohydrates to be consumed by the patient and displays a recommendation to consume number of grams **B**, step **238**. Following step **238**, the program module ends. Microprocessor **22** preferably calculates number of grams **B** in dependence upon carbohydrate value **C** and the difference between future blood glucose value  $G(t_j)$  and target blood glucose value **T** according to equation (4):

$$B = (T - G(t_j)) / C \quad (4).$$

If future blood glucose value  $G(t_j)$  is not less than hypoglycemic value **H**, then glucose value  $G(t_j)$  lies in a range between hypoglycemic value **H** and minimum value  $R_{min}$ .

In this case, microprocessor 22 displays to the patient  
"POSSIBLE FUTURE HYPOGLYCEMIA: RECOMMEND SUBSEQUENT GLUCOSE  
MEASUREMENT IN 1.5 HOURS", step 240. Following step 240,  
the program module ends. Because the patient's blood glucose  
5 concentration may rebound, it is presently preferred not to  
recommend a carbohydrate supplement unless future blood  
glucose value  $G(t_j)$  is below hypoglycemic value  $H$ .

FIG. 10 is a flow chart illustrating the steps included in  
10 the graph program module of step 220. In steps 302 - 310,  
microprocessor 22 generates a plurality of predicted future  
blood glucose values for various time points between time  $t_a$   
and time  $t_j$ . The future blood glucose values are used to  
generate blood glucose value curve 50 of graph 48. In the  
15 preferred embodiment, the future blood glucose values are  
calculated for time points which increase from time  $t_a$  to  
time  $t_j$  in five minute increments. It is obvious that the  
time increments may be varied as desired in alternative  
embodiments.

20 In step 302, microprocessor 22 sets time  $t_j$  equal to time  $t_a$   
plus five minutes. In step 304, microprocessor 22 determines  
insulin action values  $F_k(t_j)$  for each dose value  $I_k$  stored in  
memory 24. Step 304 is analogous to step 210 previously  
25 described with reference to FIG. 9A. In step 306,  
microprocessor 22 calculates future blood glucose value  
 $G(t_j)$ . Step 306 is analogous to step 214 previously  
described with reference to FIG. 9A.

30 In step 308, microprocessor 22 determines if time  $t_j$  is  
greater than or equal to the ultimate time point at which the  
last insulin dose  $k$  injected by the patient will have no  
insulin action remaining. If time  $t_j$  is not greater than or  
equal to the ultimate time point, microprocessor 22 sets time  
35  $t_j$  equal to time  $t_j$  plus five minutes, step 310.

Microprocessor 22 then repeats steps 304 - 308 to calculate a subsequent future blood glucose value.

If time  $t_j$  is greater than or equal to the ultimate time point, microprocessor 22 generates blood glucose value curve 50 from the calculated future blood glucose values and displays graph 48 on display 14, step 312. Following step 312, the graph program module ends. As shown in FIG. 1, graph 48 includes line 52 indicating the patient's hypoglycemic threshold and line 53 indicating the patient's hyperglycemic threshold. Lines 52 and 53 enable the patient to determine the time point at which he or she is predicted to develop hypoglycemia and hyperglycemia, respectively.

The diabetes management system of the present invention provides a significant improvement over conventional diabetes management systems by alerting the patient to the possible development of hypoglycemia or hyperglycemia between meals, thereby allowing the patient to take early corrective action. Conventional management systems are unable to account for the insulin action remaining from previous insulin doses and therefore restrict insulin supplements to pre-meal times. Thus, in using these conventional systems, the patient must wait until the next meal time to correct hyperglycemia, and may develop hypoglycemia without warning.

The following is an illustrative example of how apparatus 10 assists a patient in preventing hyperglycemia between meals. The example assumes the patient has an insulin sensitivity value of 40 mg/dl per unit, a target blood glucose range of 100 mg/dl - 150 mg/dl, a target blood glucose value of 120 mg/dl, a hypoglycemic value of 70 mg/dl, and a carbohydrate value of 4 mg/dl per gram.

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In the example, the patient eats a late dinner at 8:40 PM. Before eating, the patient estimates that the meal requires 15 units of bolus insulin and injects 15 units of lispro at 8:30 PM. The patient records the dose value, dose type, and  
5 time of injection in apparatus 10. At bedtime, 11:00 PM, the patient uses apparatus 10 to measure his or her blood glucose value. Apparatus 10 produces and displays to the patient a current blood glucose value of 480 mg/dl. The patient then requests apparatus 10 to predict a future blood glucose value  
10 at the ultimate time point.

Microprocessor 22 retrieves from memory 24 the dose value and corresponding insulin type of the dose injected by the patient at 8:30 PM. Microprocessor 22 calculates time after  
15 injection value  $Z_k$  to be 150 minutes. Microprocessor 22 then retrieves from Table 2 the values  $X_0 = 150$  minutes,  $Y_0 = 0.40$ ,  $X_1 = 165$  minutes, and  $Y_1 = 0.32$ . Microprocessor 22 calculates insulin action value  $F_k(t_d)$  from equation (2B) as:

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$$F_k(t_d) = 0.40 + \frac{(150 - 150)(0.32 - 0.40)}{(165 - 150)} = 0.40.$$

Microprocessor 22 thus determines that the lispro insulin dose injected at 8:30 PM has 40% of its insulin action remaining at 11:00 PM. Microprocessor 22 also sets insulin  
25 action value  $F_k(t_j)$  equal to 0.0 for each dose value stored in memory 24. For simplicity of understanding, the example assumes that only the dose injected at 8:30 PM has remaining insulin action. Microprocessor 22 then calculates the predicted blood glucose value at 3:00 AM according to  
30 equation (1) as:

$$G(t_j) = 480 - 40(15 \times .40) = 240 \text{ mg/dl.}$$



This indicates that the patient can expect an ultimate blood glucose value of 240 mg/dl when the insulin dose has been completely absorbed. The predicted value of 240 mg/dl is greater than the patient's maximum value of 150 mg/dl, so  
5 microprocessor **22** calculates a supplemental insulin dose for the patient and displays the recommended supplement on display **14**. The supplemental dose **D** is calculated from equation (3) as:

10 
$$D = (240 - 120)/40 = 3 \text{ units of supplemental insulin.}$$

The patient takes the supplemental insulin dose and records the dose value in apparatus **10**. From taking the supplemental insulin dose, the patient obtains eight hours of normal blood  
15 glucose in place of hyperglycemia. An adjusted insulin sensitivity may also be determined from the dose values and measured blood glucose values recorded in apparatus **10** as follows. The next morning, the patient measures his or her pre-breakfast blood glucose value using apparatus **10**. The  
20 patient then transmits the recorded dose values and blood glucose values measured at bedtime and before breakfast to healthcare provider computer **38**.

An adjusted insulin sensitivity value is calculated in  
25 healthcare provider computer **38** by subtracting the pre-breakfast blood glucose value from the bedtime blood glucose value. The result is divided by the total number of units of insulin which had remaining insulin action at bedtime. The  
30 number of units of insulin having remaining insulin action at bedtime is equal to the total number of units of the supplemental insulin dose plus the fraction of any previously injected insulin doses having remaining action.

An illustrative example will now be given using the same  
35 values presented above, where the patient's bedtime blood

glucose value equals 480 mg/dl, the supplemental insulin dose value equals 3 units, and the fraction of insulin action remaining from a previous 15 unit insulin dose is 0.40. The present example further assumes a pre-breakfast blood glucose value of 138 mg/dl measured the following morning. The adjusted sensitivity value is calculated as:

$$S = (480 - 138) / (3 + (15 \times 0.40)) = 38 \text{ mg/dl per unit.}$$

The insulin sensitivity value **S** is preferably updated over time as a moving average of the individually calculated sensitivity values.

A second example illustrates how apparatus **10** assists a patient in preventing hypoglycemia. The second example assumes the same values presented in the first example except that the patient's blood glucose value at 11:00 PM is now assumed to be 280 mg/dl. Microprocessor **22** calculates the predicted glucose value at 3:00 AM from equation (1) as:

$$G(t_j) = 280 - 40(15 \times .40) = 40 \text{ mg/dl.}$$

The predicted value of 40 mg/dl is less than the patient's hypoglycemic value of 70 mg/dl. Accordingly, microprocessor **22** calculates a carbohydrate supplement and displays the number of grams of carbohydrates to be consumed by the patient. The number of grams of carbohydrates is calculated from equation (4) as:

$$B = (120 \text{ mg/dl} - 40 \text{ mg/dl}) / 4 = 20 \text{ grams.}$$

The patient consumes the carbohydrate supplement and successfully avoids hypoglycemia.

#### SUMMARY, RAMIFICATIONS, AND SCOPE

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Although the above description contains many specificities, these should not be construed as limitations on the scope of the invention but merely as illustrations of the presently preferred embodiment. Many other embodiments of the invention are possible. For example, the system of the invention may be implemented in many different hardware configurations. It is presently preferred to provide the patient with a small, portable apparatus to facilitate use of the apparatus throughout the day. However, in alternative embodiments, the apparatus may comprise a personal computer, a multi-media processor connected to a television, or any other electronic device capable of performing the functions described.

Additionally, the system is not limited to establishing a communication link between the apparatus and healthcare provider computer through a telephone line or data connection cord. Those skilled in the art will recognize that the apparatus may be placed in communication with the healthcare provider computer through a computer network, a wireless communication network, or a data storage card, such as a smart card, exchanged between the physician and patient. Specific techniques for establishing communication links between a physician and a remotely located patient are well known in the art.

The insulin sensitivity values and insulin action values for determining remaining insulin action may differ in alternative embodiments. The values shown in the preferred embodiment are exemplary of one possible embodiment of the invention and are not intended to limit its scope. Further, the insulin action values may be derived from standard data or derived from the blood glucose values and insulin dose values of an individual patient. The insulin action values

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may be further customized to the individual patient in dependence upon the patient's preferred mode of insulin administration, e.g. syringe injections into the thigh, gut, or arm, insulin pump administrations, or inhalation.

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Further, the insulin action values need not be stored in tabular form. In an alternative embodiment, the apparatus stores first and second mathematical equations derived from the insulin action curves. The first equation expresses  
10 remaining insulin action as a function of time after injection of a dose of regular insulin. The second equation expresses remaining insulin action as a function of time after injection of a dose of lispro insulin. In this embodiment, the apparatus determines an insulin action value  
15 by determining the time after injection and calculating the insulin action value using the equation corresponding to the type of insulin injected.

The preferred embodiment includes a patient-operated  
20 apparatus and a healthcare provider computer in communication with the apparatus. This configuration of system components is presently preferred for ease of setting, storing, and adjusting the target blood glucose value and insulin sensitivity value of the patient under the supervision of a  
25 healthcare provider. However, those skilled in the art will recognize that the apparatus itself may also be programmed to adjust the patient's insulin sensitivity value based upon the stored blood glucose values and insulin dose values, eliminating the need for the healthcare provider computer if  
30 physician review is deemed unnecessary.

It is presently preferred to include a blood glucose meter in the apparatus for automated entry of blood glucose values. However, the apparatus need not include a blood glucose  
35 meter. In one alternative embodiment, the blood glucose

meter is separate from the apparatus and the patient manually enters measured blood glucose values into the apparatus through the keypad. In another embodiment, the blood glucose meter is connectable to the apparatus through a serial

5 input/output port for automated uploading of the blood glucose values. Similarly, in embodiments of the apparatus which include a modem, the modem need not be built into the apparatus. In alternative embodiments, the apparatus may be adapted to receive a separate modem card, as is well known in  
10 the art.

Moreover, the apparatus is not limited to storing patient data relating only to blood glucose and insulin dose values. In alternative embodiments, the apparatus also stores  
15 guidelines for diet, exercise, and other therapy parameters. Further, the apparatus may be programmed to prompt a patient for data relating to the therapy parameters and to display recommended guidelines to the patient.

20 Additionally, the invention may also be implemented as a simulation system for educating and training patients in blood glucose control. In the simulation embodiment, the insulin dose values are representative of simulated insulin doses and the blood glucose values are representative of  
25 simulated blood glucose concentrations. The patient enters various insulin dose values and blood glucose values in the simulation system to learn their effect on his or her future blood glucose concentration.

30 Therefore, the scope of the invention should be determined not by the examples given but by the appended claims and their legal equivalents.